FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMA X-16903 U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5)

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) **CONCERNING A FILING UNDER 35 U.S.C. 371** 

INTERNATIONAL APPLICATION NO. PCT/US2004/024387

OFFICE (MODIFIED)

INTERNATIONAL FILING DATE

18 August 2004 (18.08.04)

LD/566012

20 August 2003 (20.08.03)

TITLE OF INVENTION: COMPOUNDS, METHODS AND FORMULATIONS FOR THE ORAL DELIVERY OF A

GLUCAGON LIKE PEPTIDE (GLP)-1 COMPOUND OR AN MELANOCORTIN 4 RECEPTOR (MC4) AGONIST   PEPTIDE								
APPLICANT(S) FOR DO/EO/US.: Louis Nickolaus Jungheim; John McNeill McGill III; Kenneth Jeff Thrasher;								
Robert Jason Herr; Muralikrishna Valluri  Applicant herewith submits to the U.S. Designated/Elected Office (DO/EO/US) the following items and other information:								
X This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.								
This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.								
2. This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.  This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay								
examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).								
4. X The US has been elected (Article 31).								
5. X A copy of the International Application as filed (35 U.S.C. 371(c)(2))								
a. is transmitted herewith (required only if not transmitted by the International Bureau).								
b. has been transmitted by the International Bureau.								
c. X is not required, as the application was filed in the United States Receiving Office (RO/US).								
A translation of the International Application into English (35 U.S.C. 371(c)(2)).								
7. X Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))								
a. are transmitted herewith (required only if not transmitted by the International Bureau).								
b. have been transmitted by the International Bureau.								
c. have not been made; however, the time limit for making such amendments has NOT expired.								
d. X have not been made and will not be made.								
8. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).								
9. X An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).								
A declaration of the inventors 35 U.S.C. 371(c)(4) was provided in the PCT Request Form.								
A copy of the International Preliminary Report on Patentability (IPRP), including any annexes, and, if not in English, a								
English language translation of the annexes to the IPER under PCT Article 36 (35 U.S.C. 371(c)(5)).								
Items 12. to 18. below concern document(s) or information included:   12.   X   An Information Disclosure Statement under 37 CFR 1.97 and 1.98.   X   Search Report from ISA/EP								
13. X An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included								
Assignment has been recorded at reel, frame								
15. X A FIRST preliminary amendment.								
A SECOND or SUBSEQUENT preliminary amendment.								
16. A Sequence Listing, 1.821 Statement, and diskette.								
17. X A power of attorney with 3.73(b) certificate								
18. X Other items or information:								
Please amend the first page of the specification by inserting the following cross-reference after the title: "This is the national phase application, under 35 USC 371, for PCT/US2004/024387, filed 18 August 2004, which, claims the benefit, under 35 USC 119(e), of US provisional application 60/496,537 filed 20 August 2003."								

IAP20 REC'S POTITTO 25 JAN 2006

			INTERNATIONAL PCT/US2	APPLICATION N 2004/024387	NO. ATTORNEY'S DOCKET NUMBE X-16903				
19.	X The following	ng fees are submitted:			CA	LCULATIONS	PTO USE ONLY		
(a)				\$300.00		300.00			
(b)	Examination fee (37 CFR 1.492(c))						:		
	If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)					200.00			
(c)	Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)					100.00			
	Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority\$100								
	International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB\$400								
	All other situations	s		\$500					
TOTAL AMOUNT $(a + b + c) =$						900.00			
		furnishing the oath or opriority date (37 CFR)	declaration later than 30	months	\$				
HOIII tii	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	+				
Total c		19-20=		X \$50.0	0 \$				
Independent claims		7-3=	4	X \$200.0	0 \$	800.00			
MULT	IPLE DEPENDEN	T CLAIM(S) (if applied	cable)	+ \$360.0		360.00			
TOTAL OF ABOVE CALCULATIONS =						,160.00			
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).					\$	,			
SUBTOTAL =					=   \$2	,060.00			
Processing fee of \$130.00 for furnishing English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).					\$				
TOTAL NATIONAL FEE =						,060.00			
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31).  \$40.00 per property +					\$				
		<del> </del>	TOTAL FEES		= \$2	,060.00			
	· · · · · · · · · · · · · · · · · · ·				<del>-   -  </del>	Amount to be	\$		
					ļ	refunded	ļ*		
						charged	\$		
<ul> <li>a.</li></ul>									
c.	X The Commi overpaymen	ssioner is hereby autho at to Deposit Account N	rized to charge any addit Io. 05-0840. A duplicate	copy of this sheet	is end	closed.			
	(37 CFR 1.137(a	a) or (b)) must be filed	ler 37 CFR 1.494 or 1.4 l and granted to restore						
SEND ALL CORRESPONDENCE TO: ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPQLIS, INDIANA 46206-6288			Paula K Dau SIGNATURE Paula K. Davis	SIGNATURE					
	Date 47,517	<u>ry 2006</u>	317.433.3422 ELEPHONE NUMBER	· ·		25885	-		

## IAP20 Rec'd PCT/PTO 25 JAN 2006

## IN THE UNITED STATES RECEIVING OFFICE (USRO)

Applicant(s): Louis Nickolaus Jungheim, et. al. International Application No: PCT/US2004/024387

Filed: 18 August 2004

Invention: COMPOUNDS, METHODS AND FORMULATIONS FOR THE ORAL DELIVERY OF A GLUCAGON LIKE PEPTIDE (GLP)-1 COMPOUND OR AN

MELANOCORTIN 4 RECEPTOR (MC4) AGONIST PEPTIDE

Lilly Reference:

X-16903

Earliest Priority Date: 20 August 2003

Certificate Under 37 C.F.R. § 1.10

Attention: DO/EO Mail Stop PCT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

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"Express Mail" mailing label number: <u>EV 393133036 US</u>

Date of Deposit: 24 Jun. 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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